

Appl. No. : **10/706,346**
Filed : **November 12, 2003**

REMARKS

Claims 3-21 and 86-109 were considered by the Examiner. In this paper, Applicant has amended Claims 7-11, 99, 101 and 107. No Claims have been canceled. No new Claims have been added. Therefore, Claims 3-21 and 86-109 remain pending. No new matter has been added with the amendments herein.

Summary of Office Action Dated September 11, 2007

In the Office Action, the Examiner objected to Claims 4, 7, 10, and 99 because of certain informalities. The Examiner rejected Claims 3-13, 86-94, 96, 99-104 and 107-109 under 35 U.S.C. § 102(b) as being anticipated by Watkins et al. (3,995,617). The Examiner rejected Claims 15-21 under 35 U.S.C § 103(a) as being unpatentable over Waktins et al. in view of Hegde et al. (6,231,543). The Examiner rejected Claims 95, 97-98 and 105-106 under 35 U.S.C § 103(a) as being unpatentable over Watkins et al.

Regarding the Claim Objections

The Examiner objected to Claims 4, 7, 10, and 99 due to certain informalities. Claims 7 and 10 have been amended herein to make the recitation of certain limitations consistent among the claims.

Claim 4 depends from Claim 11, which recites “a discharge opening.” Accordingly, the reference in Claim 4 to “the discharge opening,” is not objectionable for the reason indicated by the Examiner.

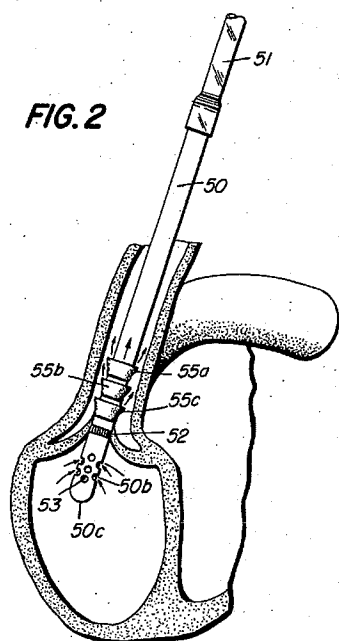
Claim 99 recites various limitations related to “*a corresponding* one of the discharge openings,” (emphasis added), therefore, it is not necessarily referring to all of the “plurality of discharge openings” recited in Claim 7, from which Claim 99 depends. Rather, it is referring to the recited subset thereof.

Accordingly, for the reasons discussed above, the objections to Claims 4, 7, 10, and 99 should be withdrawn.

Regarding the Claim Rejections

Watkins

Watkins discloses a heart assist catheter 50 for placement through the aorta and into the left ventricle (Col. 2, lines 3-7). See Figure 2, reproduced below.



An opening 50b at the distal end of the catheter 50 can withdraw blood from the left ventricle during normal systolic action of the heart. Suction of a reciprocating pump positioned at the proximal end of the catheter 50 aids this withdrawal of blood. See, e.g. Col. 5, line 48-54. During ventricular diastole, the reciprocating pump provides pressure such that the withdrawn blood is introduced into the aorta through a multiplicity of openings 50d in a wall of the catheter positioned "well back of the distal end of the catheter." (Col. 2, lines 17-22). Exterior mounted valve members, boots 55a, 55b, 55c, can open and close the multiplicity of openings depending on the suction or pressure provided by the pump within the catheter. (Col. 2, lines 8-34). Figure 2 of Watkins, illustrates the heart assist catheter as applied to a heart with arrows indicating the flow of blood from withdrawal from the left ventricle to expulsion from the catheter from the multiplicity of openings. Watkins also discloses another embodiment of catheter having a channel 57 therein that can be used to measure pressure at an end of the catheter. (Col. 4, lines 44-58; Figure 5). However, as with the embodiment of Figure 1, discussed above, the catheter of

Figure 5 can be applied to a heart to withdraw blood from the distal end of the catheter, and introduce the blood to the aorta through openings well back of the distal end of the catheter.

Regarding Claim 7

In contrast to the Watkins catheter, Claim 7 of the present application recites, among other limitations:

an elongate body having a proximal end, a distal end, and a blood flow lumen extending therethrough from an inlet located adjacent to the proximal end toward the distal end;

the cannula also comprising:

a plurality of discharge openings fluidly coupled with the blood flow lumen and located distal of the inlet; and

Watkins does not disclose discharge openings located distal of the inlet, as is recited in Claim 7. Indeed, the distal openings 50b (see Figure 2, reproduced above) of the Watkins catheter include a valve means 53 *to prevent blood* from being discharged therefrom upon application of pressure to the catheter. (Col. 3, lines 48-59). Instead, Watkins discloses discharge openings positioned proximal of the inlet. Watkins does not disclose an inlet positioned at a proximal end of the lumen, as is recited in Claim 7. Instead as noted above Watkins discloses a catheter in which the inlet is positioned at a distal end such that it can be advanced into the heart. Accordingly, for at least the reasons discussed above, Claim 7 is not anticipated by Watkins.

For at least the reasons discussed above, Claim 7 is not anticipated by Watkins. Claims 8-9 and 99-103 depend from Claim 7. Accordingly, Claims 8-9 and 99-103 are allowable for at least the reasons discussed above with respect to Claim 7.

Regarding Claim 10

In contrast to the Watkins catheter, Claim 10 of the present application recites, among other limitations, an extracardiac pumping system comprising a main cannula portion comprising a blood flow lumen extending therethrough and an inlet configured to provide fluid flow into the

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blood flow lumen and a discharge opening "located distal of the inlet." As noted above with respect to Claim 7, Watkins does not disclose a discharge opening positioned distally of an inlet of the catheter. On the contrary, Watkins discloses an inlet at a distal end thereof and a discharge opening positioned proximally thereof. Accordingly, Watkins fails to anticipate Claim 10. Thus, for release the reasons discussed above, Claim 10 is allowable over the cited art.

Regarding Claim 11

In contrast to the Watkins catheter, Claim 11 of the present application recites, among other limitations, an extracardiac pumping system comprising a percutaneous cannula with a main cannula portion comprising a blood flow lumen extending therethrough and an inlet configured to provide fluid flow into the blood flow lumen, and a tip portion extending from the main cannula portion to the distal end of the cannula and comprising a discharge opening "located distal of the inlet." As noted above with respect to Claims 7 and 10, Watkins fails to disclose a catheter having a discharge opening located distally of an inlet. Instead, Watkins discloses a heart assist catheter for direct application to a patient's heart in which the inlet, positioned at the distal-most end of the catheter, is positioned directly in the left ventricle of the patient's heart.

Accordingly, for the reasons discussed above, Claim 11 is allowable over the cited art. Claims 3-6, 12-14, 86-96, 104, and 107-109 depend from Claim 11 and recite additional limitations thereon. Accordingly, Claims 3-6, 12-14, 86-96, 104, and 107-109 are allowable for at least the reasons that Claim 11 is allowable.

The Examiner rejected Claims 15-21 as being unpatentable under 35 U.S.C. § 103 over Watkins in view of Hegde. Claims 15-21 depend from Claim 11. As noted above with respect to Claim 11, Watkins fails to disclose all of the limitations recited therein. Moreover, Watkins, by disclosing a desired application to a patient's heart and aorta in which the distal end is used to withdraw blood from the heart and valved to prevent discharge therefrom, teaches away from a cannula having a discharge opening located distal of the inlet, as is recited in Claim 11. Hegde likewise fails to disclose a cannula having a discharge opening positioned distal of an inlet. Accordingly, the combination of references asserted by the Examiner fails to disclose all of limitations recited in Claim 11, and Claims 15-21, which depend therefrom.

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Thus, the combination of references suggested by the Examiner fails to disclose or suggest all of the limitations recited in Claim 11 and in Claims 15-21, which depend therefrom. Accordingly, Claims 15-21 are allowable over the cited references.

The Examiner rejected Claims 95, 97-98, and 105-106 as being unpatentable over Watkins. Claims 95, 97-98, and 105-106 all depend from Claim 11 and recite additional limitations thereon. Accordingly, for at least the reasons noted above with respect to Claim 11, Watkins fails to disclose all of the limitations recited in Claims 95, 97-98, and 105-106. Furthermore, for at least the reasons noted above with respect to Claims 15-21, Watkins fails to suggest an extracardiac pumping system as is recited in Claim 11, from which Claims 95, 97-98, and 105-106 depend. Accordingly, for at least these reasons, Claims 95, 97-98, and 105-106 are allowable over the cited art.

Co-Pending Applications of Assignee

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial No.	Docket No.	Title	Filed
10/078,283	FORFLOW.008CP1	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	Feb. 14, 2002
11/417,652	FORFLOW.8CP1DV1	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	May 3, 3006
11/417662	FORFLOW.8CP1DV2	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	May 3, 3006
11/417918	FORFLOW.8CP1DV3	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	May 3, 3006
11/418377	FORFLOW.8CP1DV4	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	May 3, 3006
11/417647	FORFLOW.8CP1DV5	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	May 3, 3006
11/417937	FORFLOW.8CP1DV6	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	May 3, 3006
11/417487	FORFLOW.8CP1DV7	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	May 3, 3006
11/418489	FORFLOW.8CP1DV8	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	May 3, 3006
11/417916	ORQIS.007C1	CANNULAE HAVING A REDIRECTING TIP	May 3, 3006

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11/417510	ORQIS.007C2	CANNULAE HAVING A REDIRECTING TIP	May 3, 3006
11/417528	ORQIS.007C3	CANNULAE HAVING A REDIRECTING TIP	May 3, 3006
11/417877	ORQIS.007C4	CANNULAE HAVING A REDIRECTING TIP	May 3, 3006
11/417678	ORQIS.007C5	CANNULAE HAVING A REDIRECTING TIP	May 3, 3006
10/866535	ORQIS.021A	CANNULAE HAVING REDUCED FLOW RESISTANCE	June 10, 2004

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

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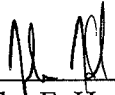
The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, John F. Heal at (949) 721-7615 to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 3/11/2008

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AMEND

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